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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,952	09/08/2004	Celal Albayrak	0155.00	6918

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EXAMINER

AUDET, MAURY A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,952

Applicant(s)

ALBAYRAK, CELAL

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1-11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/21/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of the species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide in the reply filed on 07/24/2006 is acknowledged. The traversal is on the ground(s) that 1) the groups should be examined together, and 2) a species election is improper because all species of the genres (active agent/polymer) are sought for the claimed invention. The Examiner is unclear on the traversal. As to 1) above, all claims 1-11 are a single group with only a species election required, thus any groups that may be separable therein, have not been delineated, and the traversal is deemed a moot issue. Likewise, as to 2), all species will be examined in turn, assuming the elected species (and later searched species thereafter) are found to be free of the art. A species election is merely a starting point upon which a search and examination on the merits may commence. Thus, the traversal of the species election is deemed a moot issue as well.

However, as to the species election requirement, it is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwatwar et al. (US 20030049320) in view of Yeh et al. (US 5869103).

Bhagwatwar et al. teach a method of forming microparticles comprising the elected species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide (e.g. para 158, claims 8, 26, 37, and 47), with any suitable solution/solvent well known in the art (e.g. para 2-5, 40, 75, entire document), and contemplating any well known microparticle size well known in the art for the use of microparticles in vivo. Bhagwatwar et al. teach microparticles, but does not expressly teach that microparticles includes the species nanoparticles and specific size ranges under 1 um, was not expressly found therein (e.g. Applicant's claim 11).

Yeh et al. teach the formation of nano/microparticle, which comprises active substances and the polymer poly-DL-lactide-co-glycolide, including in size ranges less than 1 um (e.g. col. 1, col. 3, lines 35-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a microparticle under 1 um or a nanoparticle comprising active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide in Bhagwatwar et al., because Yeh et al. teach that microparticles are often defined to include species of nanoparticle size, including under 1 um, and one of skill in the art would have been motivated to manufacture such, depending on the size/form most suitable for the use in question, based on the teachings of Bhagwatwar et al. to a method of forming microparticles comprising the elected species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide, with any suitable solution/solvent well known in the art

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that the claimed invention is extremely broad. As Applicant pointed out in the restriction response, the claims are directed to any nano/microparticle with any active agent and any polymer therein. However, breadth is not indefinite per se. Where the claims lack clarity though is the use of solutions/solvents by which the nano/microparticles are formed. Namely, claim 1 is drawn to an active substance in *any solution* and a polymer in an organic solvent. While claim 2 is drawn to the active substance being dissolved in *any solvent* as opposed to merely *any solution*. It is unclear what sort of solution/solvent the active substance is to be dissolved in?

Claim 5 is unclear as to what organic solvent(s) the claims are directed to? Namely, solvent(s) associated with the polymer only, or also solvent(s) that may constitute a/the solution/solvent associated with the active substance?

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In essence, the claims are wholly unclear as to what solutions/solvents are to be used in the active substance component versus the polymer substance component? The specification and claims were not found to clarify this issue. Does Applicant contemplate that virtually any solution/solvent may be used with either the active substance or the polymer as to the broad claim 1 (while as to claim 2, the L2 solvent for the polymer be a non-solvent for the active substance, whatever Applicant actually contemplates here?).

Based on the aforementioned, only a very broad search and examination of the present application could be undertaken, as set forth herein. And in this instance, the breadth of the claims and the looseness of the innumerable genus of compounds that may be used as a solution/solvents herein, render it wholly unpredictable by one of skill in the art as to whether a nano/microparticle made/used by said skilled artisan would even infringe upon the presently claimed invention.

Claim Objections

Claims 4-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not be depended therefrom. See MPEP § 608.01(n). Appropriate correction is required.

Conclusion

No claims are allowed.

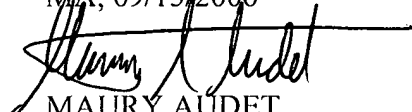
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 09/15/2006


MAURY AUDET
PATENT EXAMINER
ART UNIT 1654